Gp 1652

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PTO/SB/21 (08-00)
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Application Number	09/707,121
Filing Date	Nov 6, 2000
First Named Inventor	Mathur, Brian
Group Art Unit	1652
Examiner Name	Y. Pak
Attorney Docket Number	LEX-0083-USA

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☒ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Assignment Papers *(for an Application)*
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- ☐ Power of Attorney, Revocation Change of Correspondence Address
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm *or* Individual name	Lance K. Ishimoto Reg. No. 41,866 Lexicon Genetics Incorporated
Signature	Peter G. Sefarian Reg. No. 40162
Date	November 27, 2002

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202 on this date: November 27, 2002

Typed or printed name	Nancy Stacey		
Signature		Date	November 27, 2002

#19/Rw
12-26-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Mathur, *et al.* Group Art Unit: 1652

Serial No.: 09/707,121

Examiner: Y. D. Pak

Filed: November 6, 2000

For: NOVEL HUMAN KINASE PROTEIN AND POLYNUCLEOTIDES ENCODING THE SAME

Attorney Docket No.: LEX-0083-USA

RESPONSE TO OFFICE ACTION DATED AUGUST 27, 2002

Commissioner for Patents
Washington, D.C. 20231

Sir:

The Applicants acknowledge the receipt of the Office Action mailed on August 27, 2002 (Paper No. 18), which has been carefully reviewed and studied. The Applicants respectfully submit the following evidence and remarks and respectfully request reconsideration of the application in view of the same. In order to facilitate the Examiner's evaluation of the application, Applicants have attempted to address the rejections in Paper No. 18 in the same order in which they were originally raised.

Applicants believe that this response is filed in a timely manner and that no additional fee is due in connection with this response. However, the Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 50-0892.

I. Status of Claims

Claims 2-4 are pending in the instant application.

RESPONSE

II. Rejections Under 35 U.S.C. § 101

Claims 2-4 continue to be rejected under 35 USC section 101, as being allegedly not supported by a specific and substantial utility or a well-established utility. The Examiner's rejection is respectfully traversed, based on the following arguments as well as those presented in earlier responses.

Claims 2-4 are said, in the Action, to be drawn to polynucleotides of unidentified function (page 2, last paragraph). This is hard to believe, given the disclosure in the specification which repeatedly describes the molecules of the present invention as a novel human kinase. In addition, Applicant's previous responses which clearly reiterate Applicant's position and assertion that the molecules of the present invention encode a human kinase with all the utility that is well-recognized by the art.

The Action notes that Applicant has argued that the polypeptide of SEQ ID NO:2 is a kinase by citing WO 01/66594 and WO 02/10401 (page 4, last paragraph). This is true. These Applications clearly indicate that those of skill in the art, whom are independent and in no was associated with Applicant, have also identified the molecules of the present invention as those of a kinase. The Action states (page 5, lines 4-6) that "If one were to follow the applicant's line of reasoning, SEQ ID NO:1 could be identified as a Rab GTPase" as SEQ ID NO:1 it is 99.2% identical to a Rab GTPase. In fact, it is logical to assume that if a polynucleotide is 99.2% identical to a known polynucleotide, whose function has been identified that the heretofore unknown polynucleotide encodes a slight variant or isoform of the known molecule with a similar function. Thus, this information clearly indicates that Applicants assertion is indeed credible. Particularly in light of the indication in the recent PTO guidelines, which identifies 85% homology as being significant. Rab proteins are known to the art as small-molecular-weight GTPases that control vesicular traffic in eukaryotic cells. If SEQ ID NO:1 it is 99.2% identical to a known Rab GTPase, then it is logical to assert that the protein encoded by SEQ ID NO:1 is involved in the control of vesicular traffic in eukaryotic cells.

Furthermore, as additional evidence regarding the function and utility of the molecules of the present invention, a knockout mouse has been made in which the mouse gene homologous to that represented by SEQ ID NOS:1 and 2 was disrupted by retroviral insertion- gene trapping. These knockout mice were subject to a medical work-up using an integrated suite of medical diagnostic procedures designed to assess the function of the major organ systems in a mammalian subject.

Disruption of the mouse homolog of the human kinase gene of the present invention and the protein it encodes resulted in reduced viability, with death frequently occurring prior to birth. All of the surviving knockout mice were small and shakey, became ill, and died between 3 to 6 weeks of age. Obvious retinal blood vessel attenuation was noted in more than half of the knockout mice analyzed. Gross and microscopic pathologic examination of the sick animals revealed thymic necrosis and signs of terminal anorexia, including a generalized absence of body fat, an absence of ingesta in the gastrointestinal tract, and hyperkeratosis of the forestomach.

Applicants submit that in light of the well known utility of enzymes of this class as valuable drug targets, the Action's identification of the present invention as a molecule which has well-established utility and the identification of the disorders resulting from the disruption of the mouse homolog of the sequences of the present invention, it is clear that the sequences of the present invention represent molecules with a credible, specific, substantial and well-established utility. In light of the evidence presented above and in previous responses, Applicants respectfully submit that the present invention is in full compliance with the provisions of 35 U.S.C. § 101, and request that the rejection be withdrawn.

III. Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 2-4 continue to be rejected under 35 USC section 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention. The Action alleges that because the claimed invention is not supported by either a specific asserted utility or a well established utility one skilled in the art clearly would not know how to use the claimed invention. Applicants respectfully submit that Claims 2-4 have been shown to have a specific, substantial, credible and well established utility have significant patentable utility for the many reasons described above in section II. Applicants therefore submit that this rejection has been thus avoided and respectfully request that the rejection of claims 2-4 under 35 U.S.C. § 112, first paragraph, be withdrawn.

IV. CONCLUSION

In view of the foregoing remarks, the Applicants believe that the application is in good and proper condition for allowance. Early notification to that effect is earnestly solicited.

If Examiner Pak feels that a telephone call would expedite the consideration of the application, the Examiner is invited to call the undersigned attorney at (281) 863-3333.

Respectfully submitted,

November 27, 2002
Date

Atty Solicitation Reg No 40162
Lance K. Ishimoto by Peter C.
Lance K. Ishimoto Reg. No. 41,866

LEXICON GENETICS INCORPORATED
(281) 863-3333